



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Bruce Lester, Ph.D.
Vice President, Research and Development
SterilMed, Inc.
11400 73rd Avenue North
MINNEAPOLIS MN 55369

Re: K012556 - Supplemental Validation Submission

Trade/Device Name: See Enclosed List

Regulation Number: 21 CFR 876.5010

Regulation Name: Biliary catheter and accessories

Regulatory Class: II

Product Code: NML

Dated: April 12, 2002

Received: April 16, 2002

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on April 29, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

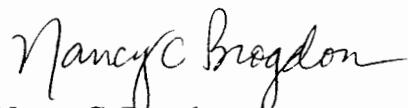
If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
<http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Attachment - Reprocessed Guidewires
(K012556)**

Microvasive

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Indications for Use

510(k) Number (if known): K012556

Device Name: Reprocessed Guidewire

Indications For Use:

Reprocessed guidewires are intended to be used for selective cannulation of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012556

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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis MN, 55369
Ph: 888-856-4870
Fax: 763-488-3350

Date Prepared: August 6, 2001

Trade Name: Reprocessed Guidewire

**Classification Name:
and Number:** Guidewire
Class II, 21CFR §876.5010 & 21CFR §876.1500

Product Code: FGE & KOG

Predicate Device(s): The reprocessed guidewire is substantially equivalent to the Jagwire™ guidewire (K922302) manufactured by Microvasive, and the FlexFinder® Guidewire (K964955) manufactured by FlexMedics.

Device Description: Reprocessed guidewires are constructed utilizing a metal alloy that is encapsulated in a striped covering and contains a radiopaque tip. The guidewires are manufactured in a wide range of diameters, lengths, tip angles, and stiffness.

Intended Use: Reprocessed guidewires are intended to be used for selective cannulation of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

K012556

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Functional and Safety Testing:

Representative samples of reprocessed guidewires underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

The reprocessed guidewire is substantially equivalent to the Jagwire™ guidewire (K922302) manufactured by Microvasive, and the FlexFinder® Guidewire (K964955) manufactured by FlexMedics.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and methods of construction.